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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/618,596 07/17/00 MACINA

R DEX-0075

EXAMINER

HM12/0925

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HARRIS, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

09/25/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/618,596

Applicant(s)

MACINA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-5 are pending.  
  
Claims 1-5 have been amended.  
  
Claims 6-12 have been cancelled.  
  
Claims 1-5 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 U.S.C. § 102***

3. The rejections of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,733,748 (filed June 6, 1995) or WO 96/39419 (Document AD on IDS) are withdrawn in view of Applicants' amendments to the claims. However, these rejections of claim 1 and 2 will be reinstated upon the deletion of the new matter of said claims.

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***Claim Rejections - 35 U.S.C. § 103***

4. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,733,748 (filed June 6, 1995) and WO 96/39419 (Document AD on IDS) are withdrawn in light of Applicants' amendments to the claims. However, this rejection of claim 1 and 2 will be reinstated upon the deletion of the new matter of the claims.

***Maintained Rejections***

***Claim Rejections - 35 U.S.C. § 112***

5. The rejection of claims 1-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Claim 7 has been canceled.

Applicants assert that the claims have been amended to specify that CSG is a protein expressed by a colon specific gene. This argument is found unpersuasive.

Claims 1-5 continue to be deemed vague and indefinite in the recitation "CSG". The language Applicants assert has been added to the claims via amendment is not present. "CSG" is an abbreviation whose identity could be chronic septic granulomatosis or chondroitin sulfate and gelatin, for example. The applicant is advised to amend the claims to include the full terminology. Applicants can obviate this rejection by amending the first claim to recite "colon specific gene (CSG)".

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***New Grounds of Rejection***

***Claim Rejections - 35 U.S.C. § 112***

6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Applicants' have amended the claims with the addition of "comprising a polynucleotide sequence or its complement capable of hybridizing under stringent conditions with SEQ ID NO:1, or a polypeptide encoded thereby", "a second sample of cells" and "first sample as compared to the second sample". Applicants have not pointed out in the amendment filed July 5, 2001 where support for this language can be found in the specification. Applicant is required to cancel the new matter in the reply to this Office action if proper support for the amendments is not provided.

***Claim Rejections - 35 U.S.C. § 102***

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,733,748 (filed June 6, 1995). U.S. Patent #5,733,748 discloses methods for diagnosing the presence of colon cancer and metastases of colon cancer in a patient (see Abstract; column 1, paragraph 1; bridging paragraph of columns 7 and 8). These methods are based on determining the levels of CSG in samples from a patient's cells, blood and saliva, for example (see column 8,

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lines 30-32; column 9, lines 17-20), determining levels of a CSG comprising a polynucleotide sequence such as GCT (see columns 29 and 30, SEQ ID NO:1, nucleic acid residues 9-11 and 13-15) that would hybridize under stringent conditions with SEQ ID NO:1 and comparing the levels of CSG between colon cancer samples (first sample) and non-diseased samples (second sample), see column 8, lines 10-16.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/39419 (Document AD on IDS). WO 96/39419 discloses methods for diagnosing the presence of colon cancer and metastases of colon cancer in a patient (see Abstract; page 1, paragraph 1; page 14, paragraph 1). These methods are based on determining the levels of CSG in samples from a patient's cells, blood and saliva, for example (see page 14, last paragraph; page 15, first paragraph; page 34, second paragraph), determining levels of a CSG comprising a polynucleotide sequence such as GCT (see Figure 1, first line, nucleic acid residues 9-11 and 13-15) that would hybridize under stringent conditions with SEQ ID NO:1 and comparing the levels of CSG between colon cancer samples (first sample) and non-diseased samples (second sample) (see page 14, paragraph 2, sentence 4).

***Claim Rejections - 35 U.S.C. § 103***

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,733,748 (filed June 6, 1995) and WO 96/39419 (Document AD on IDS). The

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teachings of the recited patent and WO document have been listed above. Neither one of these references teach methods of staging colon cancer in a patient, monitoring colon cancer in a patient, nor monitoring a change in stage of colon cancer in a patient comprising determining CSG levels in samples and periodically comparing said levels with levels of a normal human control, wherein an increase of CSG levels may be indicative of a relapse, metastasis or progression.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the methods of staging and monitoring colon cancer in a patient for changes in staging as well as for the onset of metastasis considering the methods of diagnosing the presence of colon cancer and metastases have been well established. One of ordinary skill in the art would have been motivated to continue sampling CSG levels from a patient with colon cancer in order to establish a prognosis and chart the disease. Moreover, one of ordinary skill in the art would have had a reasonable expectation of success implementing the methods of staging and monitoring colon cancer since it had been well established in the diagnosis of cancer and methods involving the practice of comparing diseased CSG samples versus control samples in these methods since the time the claimed invention was made.

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*Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
September 19, 2001

  
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